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10/520,327	10/03/2005	Akio Inui	480.1001	7240
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Davidson, Davidson & Kappel, LLC				
485 7th Avenue				
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New York, NY 10018				
EXAMINER				
DANG, IAN D				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,327

Applicant(s)

INUI ET AL.

Examiner

IAN DANG

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 10 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 4 and 10 is/are rejected.
7) ☒ Claim(s) 4 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 05 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date 05/09/2008
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/26/2008 has been entered.

Status of Application, Amendments and/or Claims

The amendment of 26 September 2008 has been entered in full. Claims 1-3, 5-9, and 11-13 have been cancelled.

Claims 4 and 10 are under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 4 is objected to because of the following informalities: Claim 23 is indefinite because claim 4 recites "a patient of diabetes mellitus". Applicants can obviate the rejection by amending the claim with "a patient with diabetes mellitus".

Appropriate correction is required.

Rejections Withdrawn

35 USC § 112, First paragraph (Written Description)

Applicant's response and arguments filed on 09/26/2008 have overcome the rejection of claims 4 and 10 under 35 USC 112, First paragraph (Written Description). At page 4 of the response, Applicants indicate that the present invention confirms the effect of the two representative compounds as described in the working examples and that the specification of the present invention also provides clear guidelines on how to screen for ghrelin analog antagonist. The rejection of claims 4 and 10 under 35 USC 112, First paragraph (Written Description) has been withdrawn.

35 USC § 112, First paragraph (Enablement)

Applicant's response and arguments filed on 09/26/2008 have overcome the rejection of claims 4 and 10 under 35 USC 112, First paragraph (enablement). At page 4 of the response, Applicants indicate that the present specification also provides sufficient description regarding to ghrelin analog antagonist (See, for example, page 11, lines 8-14) and also provides description regarding a side chain (See, for example, page 11, lines 15 to bottom). In addition, Applicants indicate that the claimed method using [D-Lys-3] -GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P are described and enabled by the specification, for example, page 23, line 18 to page 25, line 20. The rejection of claims 4 and 10 under 35 USC 112, First paragraph (enablement) has been withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (US 2001/0020012 A1, published September 6, 2001, filed January 29, 2001).

At page 5 of the response, Applicants indicate argue the fact that diabetes mellitus is associated with elevated blood glucose concentration does not lead to a conclusion that a drug useful in the treatment of diabetes necessarily lowers blood glucose level and provide the reference International Patent Publication WO 01/87335, which was cited in the International Search Report, states that the administration of GHRP-2, which is a GHS-R agonist, increases fat mass and bone mass (See for example, page 19, lines 19-20), but plasma levels of insulin and glucose were not changed by the administration of GHRP-2 (See, for example, page 20, lines 6-11). Therefore, suppressing lipid anabolism does not translate into a rise in a blood glucose level. Thus, those skilled in the art would not correlate inactivation of GHS-R with the lowering of blood glucose level.

Applicants' response and arguments have been fully considered but are not found persuasive. Although the reference WO 01/87335 indicates that the administration of GHRP-2 does not change the plasma levels of insulin and glucose, this evidence does not affect the claimed invention, since GHRP-2 is a GHS-R agonist and not a GHS-R antagonist as recited in claim 4. The therapeutic effects of a GHS-R agonist may be different from those of a GHS-R antagonist.

Therefore, the reference by Andersen et al. still anticipates the claimed invention of this application by teaching a method for treatment of Type II diabetes (page 1, paragraph [0013])

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with the antagonist for the receptor GHS-R 1A (page 2, paragraph [0022]), which a ghrelin analog antagonist. Although the reference is silent upon lowering blood glucose, the administration of a GHS-R antagonist for the treatment of diabetes would inherently result in lowering blood glucose level, as required by the claim 4, since elevated blood glucose is an important symptom of diabetes mellitus.

In addition, at page 6 of the response Applicants argue that to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by person of ordinary skill. As stated in In re Oelrich, inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. See In re Oelrich, 666 F.2d 578, 581- 82, 212 USPQ 323,326 (CCPA 1981). Therefore, in order to conclude by the logic of inherency that GHS-R antagonist lowers blood glucose level based on the disclosure of Anderson, the examiner is required to show that one of ordinary skill in the art who reads Anderson will recognizes that GHS-R antagonist lowers blood glucose level. The Examiner has failed to meet this burden.

Applicants' argument and response have been fully considered but are not found persuasive. Although Applicants cite that inherency may not be established by probabilities or possibilities, Applicants demonstrate that the characteristics of the compound are factual, not probably or possible. Therefore, there is no question as to whether or not the "certain thing" may occur, since it has been shown that it does.

It is noted that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old

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composition patentably new to the discoverer. *Atlas Powder Co. v Ireco Inc.* 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
November 5, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647